UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF NEW YORK
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DAVID N. SHEINFELD,
Plaintiff(s),

23-cv-1622 (AT) (VF)

v.

REPORT & RECOMMENDATION

B. BRAUN MEDICAL, et al.
Defendant(s).
----------X
VALERIE FIGUEREDO, United States Magistrate Judge

TO: THE HONORABLE ANALISA TORRES, United States District Judge.

On March 12, 2024, the Honorable Analisa Torres granted a motion to dismiss filed by Defendants B. Braun Medical, Inc. and Aesculap Inc. (collectively, "Defendants"). See ECF No. 40. The Court dismissed the complaint of *pro se* Plaintiff David N. Sheinfeld and gave Sheinfeld an opportunity to move for leave to amend his complaint to fix the deficiencies in his claims that were highlighted in a Report and Recommendation issued by the Honorable Ona T. Wang. See ECF No. 32. Presently before the Court is Plaintiff's motion for leave to file an amended complaint. See ECF No. 41. For the reasons set forth below, I respectfully recommend that Plaintiff's motion be **DENIED**.

BACKGROUND

A. Factual Background[1]

On November 25, 2019, Plaintiff David Sheinfeld underwent spinal disc replacement surgery at the Hospital for Special Surgery in Manhattan. ECF No. 1. at ¶ 3. The surgery utilized

[1] A full recitation of the factual background of this case is recounted in the Report & Recommendation of Judge Wang, familiarity with which is presumed. See ECF No. 32 at 1-2. Any facts recounted herein are drawn from Plaintiff's original complaint and his brief in support of his motion for leave to amend, as Plaintiff did not include a proposed amended complaint with his motion papers. See ECF Nos. 1, 41.

the ActivL Artificial Disc Class III medical device ("ActivL Device") designed and manufactured by defendant Aesculap, Inc., a subsidiary of defendant B. Braun Medical Inc. Id.

On February 25, 2020, Plaintiff attended a follow-up visit with his doctor, who determined that the disc had migrated approximately 1 mm and the device was no longer in a "safe position." Id. ¶ 5. Plaintiff alleges that the disc's migration was caused by the detachment of three spikes which fixed the device's endplate to his vertebrae. ECF No. 41 at 1-2. Plaintiff's surgeon determined that corrective surgery was necessary to avoid "catastrophic injury," and the surgery to fuse the ActivL Device in place was performed on February 28, 2020. ECF No. 1 at ¶¶ 5-6.

On April 14, 2020, Plaintiff, "as a result of the subsequent failure of the fusion hardware," underwent a second corrective surgery with a new surgeon at Inova Fairfax Hospital in Virginia. Id. at ¶ 7. Plaintiff's surgeon stated that "the migration of the disc was due to a failure of the device." Id.

B. Procedural Background

On February 24, 2023, Plaintiff commenced this action against Defendants, alleging that the failure of the ActivL Device was due to negligent design or negligent manufacturing. ECF No. 1 at ¶ 9. Plaintiff also asserted that Defendants failed to properly warn consumers of the potential risks and adverse effects of the device. Id. ¶ 8.

On April 13, 2023, Defendants moved to dismiss the complaint under Federal Rules of Civil Procedure 12(b)(2) and 12(b)(6). ECF No. 9. On May 26, 2023, Judge Wang recommended that Defendants' motion to dismiss be granted in its entirety. ECF No. 32 at 5. Judge Wang recommended dismissal of Plaintiff's state-law claims for design and manufacturing defect, concluding that the claims were preempted by the "Medical Device Amendments" ("MDA") to

the Federal Food, Drug, and Cosmetic Act ("FDCA"), 21 U.S.C. § 360k(a), because Plaintiff had not identified a specific federal requirement that the ActivL Device had failed to meet. See ECF No. 32 at 6-7. Judge Wang further recommended that Plaintiff's claim premised on a failure to warn should be dismissed because "the [A]ctivL Device's Potential Risks and A[d]verse Effects statement expressly warned that migration of the device after surgery was possible," and Plaintiff had not plausibly alleged that "the lack of a more specific warning *caused* his injury." Id. at 10 (emphasis included). Judge Wang recommended that Plaintiff be given an opportunity to amend his manufacturing defect claim. Id. at 11-12.

On March 12, 2024, the Honorable Analisa Torres adopted Judge Wang's Report and Recommendation in its entirety and granted Plaintiff until April 16, 2024, to file a motion for leave to amend his complaint. ECF No. 40 at 4. On April 8, 2024, Plaintiff filed the instant motion for leave to file an amended complaint. ECF No. 41. On April 3, 2024, Defendants filed an opposition to Plaintiff's motion, contending that any amendment would be futile. ECF No. 43 at 4-13. On April 8, 2024, Plaintiff submitted a reply in further support of his motion. ECF No. 44.

DISCUSSION

A. Legal Standard

Under Rule 15, leave to amend should be "freely give[n] . . . when justice so requires." Fed. R. Civ. P. 15(a)(2). This "permissive standard," as the Second Circuit has recognized, "is consistent with [the] strong preference for resolving disputes on the merits." Williams v. Citigroup Inc., 659 F.3d 208, 212-13 (2d Cir. 2011) (internal quotation marks and citation omitted). Under Rule 15, the "only 'grounds on which denial of leave to amend has long been held proper' are upon a showing of 'undue delay, bad faith, dilatory motive, [or] futility.'"

Sacerdote v. New York Univ., 9 F.4th 95, 115 (2d Cir. 2021) (quoting Loreley Fin. (Jersey) No. 3 Ltd. v. Wells Fargo Sec., LLC, 797 F.3d 160, 190 (2d Cir. 2015)); see also Monahan v. N.Y.C. Dep't of Corrs., 214 F.3d 275, 283 (2d Cir. 2000).

"A *pro se* complaint should not be dismissed without the Court granting leave to amend at least once when a liberal reading of the complaint gives any indication that a valid claim might be stated." Chavis v. Chappius, 618 F.3d 162, 170 (2d Cir. 2010) (internal citation and quotation marks omitted). However, "leave to amend a complaint may be denied when amendment would be futile." Tocker v. Philip Morris Cos., 470 F.3d 481, 491 (2d Cir. 2006) (internal citation omitted). Even in a *pro se* case, "it is proper to deny leave to [amend] when there is no merit in the proposed amendments or amendment would be futile." Costello v. Wells Fargo Bank, NA, No. 22-CV-1528, 2023 WL 6380061, at *2 (2d Cir. Oct. 2, 2023) (quoting Hunt v. All. N. Am. Gov't Income Tr., Inc., 159 F.3d 723, 728 (2d Cir. 1998)).

When a party argues that permitting amendment to a pleading would be futile, the court must determine whether the "proposed claim could . . . withstand a motion to dismiss pursuant to [Federal Rule of Civil Procedure] 12(b)(6)." Dougherty v. Town of N. Hempstead Bd. of Zoning Appeals, 282 F.3d 83, 88 (2d Cir. 2002), abrogated on other grounds by Knick v. Twp. of Scott, Pennsylvania, 588 U.S. 180 (2019). In other words, if a proposed claim would be subject to "immediate dismissal" for failure to state a claim, the court should not permit the amendment. Jones v. New York State Div. of Military & Naval Affairs, 166 F.3d 45, 55 (2d Cir. 1999). A district court has broad discretion in ruling on a motion for leave to amend. See e.g., Gurary v. Winehouse, 235 F.3d 792, 801 (2d Cir. 2000).

B. DISCUSSION

As an initial matter, Plaintiff did not attach a copy of his proposed amended complaint to his motion papers. ECF Nos. 41, 44. Generally, "[i]n order to meet the requirements of particularity in a motion to amend, 'a complete copy of the proposed amended complaint must accompany the motion so that both the Court and opposing parties can understand the exact changes sought.'" Zito v. Leasecomm Corp., No. 02-CV-8074 (GEL), 2004 WL 2211650, at *25 (S.D.N.Y. Sep. 30, 2004) (quoting Smith v. Planas, 151 F.R.D. 547, 550 (S.D.N.Y. 1993)). However, the failure to file a proposed amended complaint "is not fatal where there is no undue prejudice to defendant." Fei v. WestLB AG, No. 07-CV-8785 (HB) (FM), 2008 WL 594768, at *2 (S.D.N.Y. Mar. 5, 2008) (internal citation omitted). Here, Plaintiff's motion and reply papers include his factual allegations in support of his motion for leave to amend and Defendants do not seek denial on the motion based on Plaintiff's failure to file a proposed amended complaint. See Jenn-Ching Luo v. Baldwin Union Free Sch. Dist., No. 12-CV-6054 (JS) (AKT), 2013 WL 4719090, at *5 n.8 (E.D.N.Y. Sept. 3, 2013) (considering *pro se* plaintiff's motion to amend absent attachment of a proposed amended complaint). As such, Plaintiff's failure to attach a copy of his proposed amended pleading is not fatal to his motion.

Plaintiff's original complaint asserted a manufacturing defect claim against Defendants. In reviewing that claim, Judge Wang concluded that Plaintiff's claim should be dismissed because it was preempted by federal law and Plaintiff had failed to state a claim. See ECF No. 32 at 7. As Judge Wang explained, common-law tort claims concerning a Class III medical device, like the ActivL Device at issue here, are expressly preempted by federal law to the extent the claims relate to the safety and effectiveness of the approved device. See id. at 4-5. Judge Wang further added that to avoid preemption, a plaintiff must allege that state law imposes standards

that are different from or in addition to the federal requirements and that the state-law claim arises out of a specific violation of federal law. Id. at 4-6.

In examining Plaintiff's manufacturing defect claim in his original complaint, Judge Wang concluded that Plaintiff's claim did not identify a specific manufacturing or design requirement imposed by federal regulation that the ActivL Device had failed to meet. Id. at 6-7. Instead, Plaintiff made the conclusory allegation that there must have been negligence in the manufacturing or design of the device because the device had migrated after surgery. Id. In recommending that Plaintiff be afforded an opportunity to amend his claim for a manufacturing defect, Judge Wang specifically instructed Plaintiff as to what he needed to allege to state a viable claim. Judge Wang directed Plaintiff to "allege facts to support both that: a) the specific [ActivL] Device implanted in his spine was defective as a result of some mishap in the manufacturing process itself, improper workmanship, or because defective materials were used in construction; and b) the defect was the cause of his injury." ECF No. 32 at 11-12.

Plaintiff's allegations do not fix the deficiencies identified by Judge Wang. Plaintiff alleges that the ActivL Device is "designed to achieve 'initial fixation of the device endplate to the vertebral body' to allow time for the endplate to fuse with the vertebrae." ECF No. 41 at 1. Pointing to X-rays, Plaintiff alleges that the ActivL Device was "only able to engage for a limited time before disconnecting from the vertebrae, failing in [its] primary purpose." Id. at 1-2. Plaintiff further asserts that "the spikes were defective and never penetrated the bone, leaving no chance for the device to fuse as designed." ECF No. 44 at 2-3. Finally, Plaintiff alleges that because his "doctor's notes" from the surgery "indicate that the device was properly installed," the failure of the device can only be attributed to improper workmanship" in the manufacturing of the device. ECF No. 41 at 2. Plaintiff adds that the "improper workmanship resulted in the

failure to produce spikes with the necessary sharpness and strength to properly function when used as directed." Id.

These allegations essentially restate those that were deemed insufficient by Judge Wang in Plaintiff's original complaint. For example, Plaintiff previously alleged that there "may have been negligence in the manufacture of this particular disc" because it did not "successfully integrate into the bone." See ECF No. 1 at ¶ 9. Plaintiff previously identified the spikes as the defective component in the ActivL Device. Id. Now, Plaintiff similarly points to the spike's failure to attach to his vertebrae to assert that the manufacturing process was defective. See ECF No. 41 at 1-2. He also identifies the spikes by name ("SW992K L11d/SPIKES"). See ECF No. 41 at 1. And Plaintiff again alleges that a manufacturing defect occurred because the spikes "were only able to engage for a limited time before disconnecting from the vertebrae, failing in their primary purpose." Id. Plaintiff, however, provides no new factual allegations to support his conclusory assertion that the failure in the spikes was attributable to any specific manufacturing defect.

Nor does Plaintiff support his claim by specifying how the manufacturing process was defective or identifying a specific failure or mishap in the manufacturing of this ActivL Device. See, e.g., Cosh v. Atrium Med. Corp., No. 18-CV-8335 (ALC), 2020 WL 583826, at *3 (S.D.N.Y. Feb. 6, 2020) (dismissing claim where plaintiff "failed to adequately allege any deviations from the manufacturing process, improper workmanship, or defective materials"); Bustamante v. Atrium Med. Corp., No. 18-CV-8395 (ALC), 2020 WL 583745, at *6 (S.D.N.Y. Feb. 6, 2020) (same); Goldin v. Smith & Nephew, Inc., No. 12-CV-9217 (JPO), 2013 WL 1759575, at *3 (S.D.N.Y. Apr. 24, 2013) (dismissing claim where plaintiff "failed to allege *any* facts regarding the manufacturing process") (emphasis included); Am. Guar. & Liab Ins. Co. v.

Cirrus Design Corp., No. 09-CV-8357, 2010 WL 5480775, at *3 (S.D.N.Y. Dec. 30, 2010) (plaintiffs failed to adequately allege deviations from the manufacturing process or improper workmanship); Koublani v. Cochlear Ltd., No. 20-CV-1741 (DRH) (AYS), 2021 WL 2577068, at *13 (E.D.N.Y. June 23, 2021) ("New York state courts themselves grant motions to dismiss for failure to state a manufacturing defect claim when the complaint does not identify a specific defect."). "[S]tating that the product was 'carelessly, negligently, and defectively designed, manufactured [and] produced[,]'" as Plaintiff summarily does here, does not suffice to "allege an error in the manufacturing process—it only states that there was one." Surdo v. Stamina Prod. Inc., No. 15-CV-2532, 2015 WL 5918318, at *5 (E.D.N.Y. Oct. 9, 2015).

There are no factual allegations, for example, that the ActivL Device was manufactured at a plant with a history of substandard practices, or that Defendants were previously subject to regulatory action relating to defects in this device. See Kulkarni v. Actavis Generics, No. 22-CV-5735 (PAE) (BCM), 2023 WL 6545603, at *7 (S.D.N.Y. Sept. 8, 2023), report and recommendation adopted by, 2023 WL 6289963 (S.D.N.Y. Sept. 27, 2023) (dismissing plaintiff's claim where she did not allege facts sufficient to "show that the tablets she took were produced in a plant at which unsafe or substandard practices were used."); Ortiz v. Allergan, Inc., No. 14-CV-8188 (PAC), 2015 WL 5178402, at *5 (S.D.N.Y. Sept. 4, 2015) ("While an FDA warning letter or recall is not *required* to state a manufacturing defect claim, the existence of such actions provides factual support for the claim that a defendant's manufacturing process is flawed, making a manufacturing defect claim significantly more plausible.") (emphasis included); Green v. Covidien LP, No. 18-CV-2939 (PGG), 2021 WL 1198833, at *6 (S.D.N.Y. Mar. 30, 2021) (dismissing amended complaint which did not "plead facts showing how [d]efendant's manufacturing process was flawed, or in what way the mesh product at issue deviated from

[d]efendant's design"); Ainette v. Market Basket, Inc., No. 19-CV-4506 (DF), 2021 WL 1022590, at *12 (S.D.N.Y. Mar. 16, 2021) ("[Plaintiff] fails to allege any facts *at all* regarding the manufacturing process, rendering [his claim] insufficient on this basis alone.") (emphasis included) (internal citation omitted). At bottom, Plaintiff has merely restated the allegations already found to be "conclusory" and deficient by Judge Wang. See ECF No. 32 at 7.

Plaintiff has also failed to identify a specific federal requirement that the device violated, as Judge Wang explained was necessary to state a parallel state-law claim and avoid preemption. See id. Plaintiff alleges that Defendants violated 21 CFR Part 820.90, which requires a manufacturer to have procedures to "address the identification, documentation, evaluation, segregation, and disposition of nonconforming product." See ECF No. 44 at 6. First, although Plaintiff states that Defendants failed to establish and maintain procedures to control their allegedly defective product, id., that bare and unsupported assertion is insufficient to plausibly state a claim. See, e.g., Simon v. Smith & Nephew, Inc., 990 F. Supp. 2d 395, 403 (S.D.N.Y. 2013) ("Plaintiffs suing with regard to a PMA-approved device cannot simply make the conclusory allegation that defendant's conduct violated FDA regulations."); Gale v. Smith & Nephew, Inc., No. 12-CV-3614 (VB), 2013 WL 9874422, at *3 (S.D.N.Y. Sept. 13, 2013) (explaining that "to plead a claim, plaintiff cannot simply incant the magic words [defendants] violated FDA regulations in order to avoid preemption") (citation and internal quotation marks omitted); Babayev v. Medtronic, Inc., 228 F. Supp. 3d 192, 215 (E.D.N.Y. 2017) (collecting cases).

Second, the regulation that Plaintiff points to is non-specific and is "intended to serve only as an umbrella quality system, providing general objectives medical device-manufacturers must seek to achieve." Horowitz v. Stryker Corp., 613 F. Supp. 2d 271, 278-79 (E.D.N.Y. 2009)

(internal quotation marks omitted). Courts in this Circuit routinely conclude that manufacturing defect claims premised solely on violations of these types of non-specific regulations are "too generic, standing alone, to serve as the basis for . . . manufacturing defect claims." Gale, 2013 WL 9874422, at *3 (internal quotation omitted); see, e.g., Ilarraza v. Medtronic, Inc., 677 F. Supp. 3d 582, 588 (E.D.N.Y. 2009) (concluding that plaintiff's claim that defendant violated eight CGMPs was pre-empted because "no regulation relied upon refers specifically to the medical device at issue").

Attached to his motion, Plaintiff included the following: an excerpt of an "FDA Summary of Safety and Effectiveness" for the ActivL Device, ECF No. 41, Ex. 1 at 5; X-rays dated February 25, 2020, id., Ex. 2 at 6-9; physician notes describing Plaintiff's surgery, id., Ex. 3 at 10-13; and an FDA Manufacturer and User Facility Device Experience ("MAUDE") report from Defendant Aesculap AG, appearing to describe the "adverse event" of Plaintiff's specific ActivL Device, and the results of Aesculap's investigation of any manufacturing issues which affected that device. Id. Ex. 4, at 13-15. None of these documents point to a specific flaw in the manufacturing or design process, or a specific violation of a federal requirement.

Plaintiff has similarly failed to include facts from which to plausibly infer that the alleged "defect was the cause of his injury." ECF No. 32 at 12. Relying on his doctor's notes from the surgery which show that the device was "properly installed" and that Plaintiff followed appropriate procedures after the surgery, Plaintiff concludes that "failure of the device can only be attributed to improper workmanship in the manufacture of the disc." ECF No. 41 at 2. But this allegation does not provide a causal link between Plaintiff's injury and a specific defect in the device. It is the same circular allegation that Judge Wang already rejected. At best, Plaintiff's allegation only excludes "several possible causes" for Plaintiff's injury. Goldin, 2013 WL

1759575, at *3. Plaintiff does not, for example, allege that his surgeon attributed the failure of the ActivL Device to attach to his spine to a defect in the device. Id.

Moreover, any inference of a causal link between a design or manufacturing defect and Plaintiff's injuries is contradicted by evidence Plaintiff attached to his motion papers. Plaintiff provided a MAUDE, which provides information about the manufacturer's internal review of the device's quality and its manufacturing history.[2] ECF No. 41, Ex. 4, at 14. The MAUDE appears to find no issues with the device's quality and manufacturing history. Id. The MAUDE concludes that "the root cause of the problem is most probably patient and usage-related," and the report lists a number of potential causes for Plaintiff's injury unrelated to a design or manufacturing defect: "wrong system configuration selected by the user, wrong implant size chosen by the user, design layout unsuitable. . . ." Id. Plaintiff has thus failed to plausibly allege that a defect in the design or manufacturing of the ActivL Device was the sole "cause" of his injury. See Goldin, 2013 WL 1759575, at *3 (concluding that plaintiff failed to establish the absence of another possible cause for her product's failure).

A. **Leave to Amend**

Rule 15(a)(2) provides that the Court should "freely give leave" for a party to amend its pleading "when justice so requires." F.R.C.P. 15(a)(2). Leave to amend may properly be denied for "repeated failure to cure deficiencies by amendments previously allowed" or futility. Ruotolo v. City of N.Y., 514 F.3d 184, 191 (2d Cir. 2008) (citation omitted). Here, Plaintiff was already informed of the deficiencies in his claim and told how to cure them. Even with the Court's

[2] "The 'Manufacturer and User Facility Device Experience' (MAUDE) is an FDA database that contains "reports of adverse events involving medical devices." Tomaselli v. Zimmer, Inc., No. 14-CV-4474 (RA), 2015 WL 13888410, at *3 (S.D.N.Y. Mar. 23, 2015).

assistance, Plaintiff has failed to cure the deficiencies. Under these circumstances, Plaintiff should not be afforded an opportunity to amend his claims. See, e.g., Wimberly v. Experian Info. Sols., No. 18-CV-6058, 2021 WL 326972, at *1, *4-6 (S.D.N.Y. Feb. 1, 2021) (denying *pro se* plaintiff leave to amend where proposed amended complaint did not address deficient allegations previously identified); Ngambo v. Chase, No. 20-CV-2224 (NSR), 2023 WL 9004789, at *2, *5-6 (S.D.N.Y. Dec. 28, 2023) (dismissing *pro se* plaintiff's claims with prejudice where Plaintiff failed to plead facts sufficient to cure the deficiencies identified in the court's previous order). I thus recommend that Plaintiff be denied leave to amend.

CONCLUSION

For the foregoing reasons, I respectfully recommend that Plaintiff's motion for leave to file an amended complaint be **DENIED.**

DATED: New York, New York
August 27, 2024

VALERIE FIGUEREDO
United States Magistrate Judge

PROCEDURE FOR FILING OBJECTIONS TO THIS REPORT AND RECOMMENDATION

Pursuant to 28 U.S.C. § 636(b)(1) and Rule 72(b) of the Federal Rules of Civil Procedure, the parties have fourteen (14) days (including weekends and holidays) from service of this Report and Recommendation to file any objections. See also Fed. R. Civ. P. 6(a), 6(b), 6(d). A party may respond to any objections within 14 days after being served. Any objections and responses shall be filed with the Clerk of the Court. Any request for an extension of time to file objections or responses must be directed to the Honorable Analisa Torres. If a party fails to file timely objections, that party will not be permitted to raise any objections to this Report and Recommendation on appeal. See 28 U.S.C. § 636(b)(1); Fed. R. Civ. P. 72; Fed. R. Civ. P. 6(a), 6(b), 6(d); Thomas v. Arn, 474 U.S. 140 (1985); Wagner & Wagner, LLP v. Atkinson, Haskins, Nellis, Brittingham, Gladd & Carwile, P.C., 596 F.3d 84, 92 (2d Cir. 2010).